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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,716	01/26/2006	Richard Sharp	MSQ01-005-US	9797

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,716	SHARP ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/20/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-104* is/are pending in the application.

4a) Of the above claim(s) *53,54,57,58,61,63,65-90,92-95 and 98-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51,52,55,56,59,60,62,64,91,96 and 97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/2006; 5/23/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 5/28/2008 is acknowledged. The traversal is on the following ground(s):

Applicant argues:

1. That the technical feature linking the groups is not simply a bacteriophage, but the combination of a bacteriophage, a polysaccharide lyase, and an antimicrobial agent. Applicant asserts that Lee does not disclose such a combination.

2. That the GH phages of Lee are completely unrelated to the GH phages of the instant invention. Applicant argues that the GH designation is a "local" designation used by the instant inventors. Applicant also argues that the claims recite bacteriophages capable of infecting bacteria within a biofilm of a patient, such as *Pseudomonas aeruginosa*, and argues that the phages of Lee are unable to infect *Pseudomonas aeruginosa*, instead infecting *Pseudomonas putida*.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, despite applicant's assertions, the combination of a bacteriophage, a polysaccharide lyase, and an antimicrobial agent is not the linking feature of the claims. The method claims do not require administration of such a composition. They merely require administration of the components of the composition, and as evidenced by claims 81, these components do not need to be administered at the same time. Therefore, one could have three different compositions, with one containing a bacteriophage, one containing a polysaccharide lyase, and one containing an antimicrobial agent. Furthermore, the methods of making the phage do not require such a composition. The only feature that can be found in all of the groups is a bacteriophage that is capable of infecting a *Pseudomonas* bacterium in a biofilm in a patient.

Regarding argument 2, there is no mention of *Pseudomonas aeruginosa* in any of the claims and it is not a requirement of any of the groups. *Pseudomonas putida* can form biofilms and can infect humans; therefore, the phages of Lee are art over the linking feature of the claims. Applicant is correct that GH is a local designation; however, this does not render the disclosure of Lee insufficient.

The requirement is still deemed proper and is therefore made FINAL.

Previously pending claims 1-50 have been canceled and new claims 51-104 are pending. The new claims fit into the same groups set forth in the restriction requirement set forth on 3/31/2008, with the exception of Group VI, claim 57, which is not represented in the new claim set. The new claims fall into the groups as set forth here:

Claims 51-52, 55-56, 59-60, 62, 64, 91, and 96-97 are in Group I.

Claims 53 and 56 are in Group II.

Claims 54, 56, and 63 are in Group III.

Claims 57 and 61 are in Group IV.

Claim 58 is in Group V.

No claim is in Group VI.

Claims 65-66, 69, 72, 75-82, 92, 98-99, and 104 are in Group VII.

Claims 67 and 69 are in Group VIII.

Claims 68-69, 79, 76, and 83 are in Group IX.

Claims 70, 74, and 84 are in Group X.

Claim 71 is in Group XI.

Claims 85-90, 93-95, and 100-103 are in Group XII

Claims 53-54, 57-58, 61, 63, 65-90, 92-95, and 98-104 are withdrawn as being drawn to nonelected inventions. Claims 51-52, 55-56, 59-60, 62, 64, 91, and 96-97 are currently under examination.

Information Disclosure Statement

The information disclosure statements filed on 1/26/2006 and 5/23/2007 have been considered. Initialed copies are enclosed. US Patent 6,161,036, by Ghanbari *et al.* (IDS filed 1/26/2006) has not been considered, as there is no such patent by Ghanbari *et al.*

Specification

The use of the trademarks ROBBINS and APPLIKON have been noted in this application. ROBBINS appears on pages 4, 6, and 21 and APPLIKIN appears on page 21. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that the cited occurrences of improper use are only exemplary and applicant should review the specification to correct any other use of trademarks.

Claim Objections

Claim 51 is objected to because of the following informalities: The genus name, *Pseudomonas*, should be italicized. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59 and 60 are rejected 35 U.S.C.§ 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the bacteriophages with the recited accession numbers are required to practice the claimed invention. As such they must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the instantly claimed bacteriophages.

The process disclosed in the specification does not appear to be repeatable and it is not clear that the claimed method will work with commonly available material per se and it is not apparent that the source materials are readily available to the public. It is noted that Applicants have deposited the organisms but there is no proper indication in the specification as to public availability. Therefore, a deposit at a recognized depository may be made for enablement purposes.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51-52, 55, 91, and 96-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Hughes *et al.* (Bioline, pp 325-331, 2001; IDS filed 1/26/2006).

The instant claims are drawn to compositions for treating a bacterial biofilm wherein the biofilm is a biofilm of a patient, said composition comprising a bacteriophage that is capable of infecting a *Pseudomonas* bacterium, a polysaccharide lyase enzyme that is capable of degrading a polysaccharide within said biofilm, and a pharmaceutically acceptable antimicrobial agent.

Hughes *et al.* teach that application of phage carrying and encoding hydrolytic enzymes to destroy alginate biofilm (alginate lyase) offers huge therapeutic benefits and that delivery of phage in combination with other agents designed to reduce the severity of the symptoms of cystic fibrosis and bacterial colonization (such as antibiotics, DNAase or polypeptide defensins) could be used to effectively destroy lung biofilms (see page 329, paragraphs 2-3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 51-52, 55-56, 91, and 96-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes *et al.* (Bioline, pp 325-331, 2001; IDS filed 1/26/2006) in view of Wilde *et al.* (WO 89/11291A1, 1989, IDS filed 5/23/2007).

The instant claims are drawn to compositions for treating a bacterial biofilm wherein the biofilm is a biofilm of a patient, said composition comprising a bacteriophage that is capable of infecting a *Pseudomonas* bacterium, a polysaccharide lyase enzyme that is capable of degrading a polysaccharide within said biofilm, and a pharmaceutically acceptable antimicrobial agent.

Hughes *et al.* teach that application of phage carrying and encoding hydrolytic enzymes to destroy alginate biofilm (alginate lyase) offers huge therapeutic benefits and that delivery of phage in combination with other agents designed to reduce the severity of the symptoms of

cystic fibrosis and bacterial colonization (such as antibiotics, DNAase or polypeptide defensins) could be used to effectively destroy lung biofilms (see page 329, paragraphs 2-3).

Hughes *et al.* do not teach that the antimicrobial agent should be encoded by the bacteriophage.

Wilde *et al.* disclose an antimicrobial polypeptide, the sequence of said polypeptide, and expression vectors encoding said polypeptide (see abstract and page 7).

It would have been obvious to one of ordinary skill in the art, at the time of invention, to use the bacteriophage of Hughes *et al.* to encode the antimicrobial polypeptide of Wilde *et al.* because it is obvious to combine known prior art elements according to known methods to achieve predictable results. As the sequence of the antimicrobial polypeptide was known, as were the methods required to produce a recombinant phage carrying such a peptide, one of ordinary skill in the art could easily and predictably used the phage to encode the antimicrobial polypeptide.

Claims 51-52, 55, 64, 91, and 96-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes *et al.* (Bioline, pp 325-331, 2001; IDS filed 1/26/2006) in view of Nairn (Chapter 86 in Remington: The science and practice of pharmacy, Vol. II, 1995, pp 1495-1523).

The instant claims are drawn to compositions for treating a bacterial biofilm wherein the biofilm is a biofilm of a patient, said composition comprising a bacteriophage that is capable of infecting a *Pseudomonas* bacterium, a polysaccharide lyase enzyme that is capable of degrading a polysaccharide within said biofilm, and a pharmaceutically acceptable antimicrobial agent.

Hughes *et al.* teach that application of phage carrying and encoding hydrolytic enzymes to destroy alginate biofilm (alginate lyase) offers huge therapeutic benefits and that delivery of phage in combination with other agents designed to reduce the severity of the symptoms of cystic fibrosis and bacterial colonization (such as antibiotics, DNAase or polypeptide defensins) could be used to effectively destroy lung biofilms (see page 329, paragraphs 2-3).

Hughes *et al.* do not teach that the formulation should be in the form of an aerosol formulation, comprising one or more of an excipient, surfactant, and/or propellant.

Nairn teaches that inhalations are preparations used or designed so that a drug is carried into the respiratory tree of a patient (see paragraph bridging pages 1507 and 1508). Metered dose inhalers are propellant-driven drug suspensions or solutions intended for delivering metered doses of the drug to the respiratory tract (see page 1508, column 1, paragraph 2).

It would have been obvious to one of ordinary skill in the art, at the time of invention, to use a metered-dose inhaler, as disclosed by Nairn, to provide the composition of Hughes *et al*. to a patient, because the biofilm produced in a cystic fibrosis patient is in the lungs and inhalation is the simplest way to administer a drug to the lungs.

One would have had a reasonable expectation of success because metered-dose inhalers are a standard means for delivering drugs to the respiratory tract.

Claims 51-52, 55, 62, 91, and 96-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes *et al.* (Bioline, pp 325-331, 2001; IDS filed 1/26/2006) in view of Budny *et al*. (US Patent Application Publication, US 2002/0037260, 2002; IDS filed 1/26/2006).

The instant claims are drawn to compositions for treating a bacterial biofilm wherein the biofilm is a biofilm of a patient, said composition comprising a bacteriophage that is capable of infecting a *Pseudomonas* bacterium, a polysaccharide lyase enzyme that is capable of degrading a polysaccharide within said biofilm, and a pharmaceutically acceptable antimicrobial agent.

Hughes *et al.* teach that application of phage carrying and encoding hydrolytic enzymes to destroy alginate biofilm (alginate lyase) offers huge therapeutic benefits and that delivery of phage in combination with other agents designed to reduce the severity of the symptoms of cystic fibrosis and bacterial colonization (such as antibiotics, DNAase or polypeptide defensins) could be used to effectively destroy lung biofilms (see page 329, paragraphs 2-3).

Hughes *et al.* do not teach that the lyase encoded by the phage should be a heterologous lyase.

Budny *et al.* disclose compositions for treating biofilms which comprise a mixture of an antimicrobial agent and a lyase (see paragraphs 0024-0033 and 0066). Budny *et al.* disclose that alginate lyase is an expression product of the algL gene and can be obtained from various bacterial sources and the lyase can be recombinantly produced (see paragraphs 0127 and 0129).

It would have been obvious to one of ordinary skill in the art, at the time of invention, to use an alginate lyase from any of the listed sources in Budny *et al.* as a heterologous lyase encoded by the phage because it is obvious to combine known prior art elements according to known methods to achieve predictable results. As the sequence of the various lyase genes were known, as were the methods required to produce a recombinant phage carrying such a lyase, one of ordinary skill in the art could easily and predictably used the phage to encode one of the disclosed lyases.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645
/Mark Navarro/
Primary Examiner, Art Unit 1645